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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,128	11/27/2001	Alan N. Houghton	MSK.P-026-3	3698

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Marina Larson & Associates LLC
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EXAMINER	
HARRIS, ALANA M	
ART UNIT	PAPER NUMBER
1643	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/27/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/996,128	HOUGHTON ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-27,29 and 30* is/are pending in the application.

4a) Of the above claim(s) *25-27* is/are withdrawn from consideration.

5)☒ Claim(s) *24* is/are allowed.

6)☒ Claim(s) *20-23,29 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment and Arguments

1. Claims 20-27, 29 and 30 are pending.

Claim 24 has been amended.

Claims 25-27, drawn to non-elected inventions are withdrawn from examination.

Claims 20-24, 29 and 30 are examined on the merits to the extent that the xenogeneic differentiation antigen is a human tyrosinase and human gp75.

Election/Restrictions

2. Applicants revisit the Election/Restrictions requirement mailed June 25, 2004. The Examiner concurs with Applicants' citation, "...election of up to 10 sequences...", which is actually found in MPEP 2434. This quotation provides that one sequence or as many as ten sequences can examined. However, nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. SEQ ID NO: 2 is distinct from SEQ ID NO: 1 for the reasons of record and the restriction requirement is FINAl.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Maintained Rejection

Claim Rejections - 35 USC § 103

4. The rejection of claims 20-23, 29 and 30 under 35 U.S.C. 103(a) as being unpatentable over Zhai et al. (The Journal of Immunology 156: 700-710, January 1996), and further in view of U.S. Patent number 5,773,291 (filed January 23, 1995/ IDS reference, submitted May 23, 2003) and U.S. Patent number 6,080,727 (effective filing date March 26, 1996) is maintained.

Applicants reiterate the criteria necessitated for establishing a *prima facie* case of obviousness, see page 4, 5th paragraph of Remarks submitted October 18, 2006. Applicants point out primary reference, Zhai does not mention canine malignant melanoma (CMM) and secondary references, patent '291 and patent '727 also do not relate to the treatment of CNM. Applicants point out a recitation found in Zhai and assert there is a lack of congruence between the citation and what is well-known and reasonably likely to be successful, see page 5, 1st paragraph. Applicants include documents which purportedly support their argument that there is a patentable distinction between melanoma and very aggressive and hard-to-treat disease CMM. These points of view, documents and arguments have been carefully considered, but found unpersuasive.

The combination of the references meets all the requirements for a establishing a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Zhai

does such by teaching a method of inducing specific T cell immunity for mammalian metastatic melanoma treatment utilizing xenogenic melanoma-associated antigen differentiation antigens expressed in recombinant adenoviruses and consequently administering said antigens to C57BL/6 mice. The administration was successful rendering a protective affect against murine metastatic melanoma. The secondary references provide the specific xenogenic melanoma-associated differentiation antigens that were analogous to the gp100 human melanoma-associated antigen of Zhai and the effective treatment of a dog with a DNA sequence for effective melanoma treatment.

The second requirement is there must be a reasonable expectation of success. Zhai and patent '727 provide the success of mammalian treatment implementing gene therapy and patent '291 assures one of ordinary skill in the art of the high propensity that exists to express biological functional tumor-associated antigens (TAA). Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. The Examiner has met the final criteria.

Applicants assert the Examiner depends on a citation, "has opened new possibilities for the development of cancer vaccines.", but Applicants have not pointedly expressed where in Zhai this is found. Notwithstanding, the successful metastatic melanoma treatment presented in the entire article from 1996 establishes this treatment is well known and is predicated upon established xenogeneic melanoma-associated differentiation antigens.

And Applicants attempt to make distinctions between melanoma and CMM do not further their arguments. For one reason, Applicants fail to take into account Zhai teaches the treatment of patients with *metastatic* melanoma, not just melanoma in a broad sense (which does include both, benign and malignant cancer). In the 1999 Modiano reference Applicants provided October 18, 2006 it is noted that CMM is a rapidly *metastatic* disease. The *metastatic* melanoma of Zhai is within the scope of CMM. These two states of melanoma are not mutually exclusive. The Examiner has met the initial burden of providing references that expressly or impliedly suggest the claimed invention with suggestion of the desirability of doing what the inventor has done. The Examiner's statements provided in the last Action mailed July 18, 2006 and the analysis provided in the preceding paragraphs express a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references. For these reasons and those of record the rejection is maintained.

Allowable Subject Matter

5. Claim 24 is allowed.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
21 December 2006